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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/921,478 | 08/03/2001 | M. Zafar Amin Munshi | 1080.165US3 | 8167 |

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[REDACTED] EXAMINER

VIJAYAKUMAR, KALLAMBELLA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1751 | 4 |

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

D26

| | | |
|------------------------------|-------------------------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/921,478 | MUNSHI, M. ZAFAR AMIN |
| | Examiner Kallambella Vijayakumar | Art Unit 1751 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 and 26-48 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 and 26-48 is/are rejected.
- 7) Claim(s) 2 and 29 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 8/3/01 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____ |
|---|--|

Detailed Action

- The present application #09/921,478 is a divisional of #09/042,255 filed 03/13/1998, now US Patent #6,295,474.
- Acknowledge the cancellation of claims 8-25 and addition of Claims 26-48 through preliminary amendment dated 08/03/2001 in Paper #2. Claims 1-7 and 26-48 are currently pending.
- Acknowledge the amendments to the title, drawings, abstract and the specification through the preliminary amendment dated 08/03/2001 in Paper #2.
- Acknowledge the receipt of IDS submitted on 08/03/2001 in Paper #3.
- The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
- The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Claim Objections

Claims 2 and 29 are objected to because of the following informalities: Claim 2 and 29 are identical to each other. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 35, 41 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high surface area" in claims 30, 35, 41 and 46 is a relative term which renders the claim indefinite. The term "high surface area" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102
Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The use of phrase “for coating anelectrode” in the claim-1 has not been treated with patentability. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The examiner construes this language as “Intended Use” and not treated with merits for patentability.

Claims 1-7 and 26-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keusch et al (US Patent #5,354,790).

Keusch et al disclose method of making non-stringy hydrogels comprising of a homogeneous uniform mixture of polyethylene oxide (PEO) or polyvinyl pyrrolidone (PVP) in water, and optionally containing effective amount of water-soluble electrolyte to provide conductive non-stringy materials (Abstract). Keusch et al disclose a making of a skin-interfacing member of a medical electrode comprising of PVP and electrolyte (Col-9, Lines: 45-60). Further, a electro-conductive gel formulation comprised of a PEO with a molecular weight of 0.2×10^6 to 10×10^6 daltons at a concentration of 7-35 wt % of in water and 0.1-15 wt% electrolyte such as NaCl or KCl, wherein the specific concentration depended on the desired conductivity for the hydrogel (Col 21, Lines: 19-35, Col-22, Lines: 44-61). Keusch further disclose the incorporation of various additives such as stabilizers, preservatives, glycerin, pharmaceuticals, anesthetics, antimicrobials, healing agents or the like in the hydrogel (Col-16, Lines: 5-24). Keusch also

disclose the electrically conductive transparent coating for medical electrodes comprising a polymer such as PVA or polyacrylate, electrolyte such as LiCl, NaCl or KCl, plasticizer such as glycerin, PG or PEG, antifungal agent, and binder such as silica, wherein a mixed solvent of propanol and water was used in the making of the coating (Col-2, Lines: 41-46; Col-4, Lines: 30-39). Keusch further discloses the use of hydrogel coatings to bio-electrodes for various applications including defibrillation and implants (Col-26, Lines: 36-69). All the limitations of the instant claims are met.

The reference is anticipatory.

In the alternative that the disclosure by Keusch et al be insufficient to arrive at the instant claims, it is in the purview of a skilled artisan to make minor modifications in composition, optionally choose to add desired pharmaceuticals, silica, alcohol and/or other well known plasticizers in the formulation based on either the disclosure or common use in the art to obviously arrive at the instant claims of the applicants.

Claims 1-4, 26, 29, 31-33, 37, 39 43 and 47, rejected under 35 U.S.C. 102(e/a) as anticipated by Dolzhikov et al (RU 2,086,217).

Dolzhikov et al disclose a solution comprising of 0.5-10 wt% solution of polyethylene oxide (PEO) in an acetate-nitrate or phosphate buffer at a pH of 6.8-7.8 wherein the acetate-nitrate buffer contained 0.615 wt% sodium chloride, 0.39 wt% sodium acetate, 0.17 wt% sodium nitrate in water and phosphate buffer contained 0.85 wt% sodium chloride, 0.024 wt% sodium hydrogen phosphate, 0.004 wt% sodium hydrogen phosphate in water. The molecular weight limitation of the PEO would be inherent. The concentration of sodium chloride is at 0.85 wt%

that is close to the lower limit of 1.0 wt% per the instant claim limitation of in Claims 37 and 38.

All the limitations of the instant claims are met.

The reference is anticipatory

Claims 1-7 and 26-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dolzhikov et al (RU 2,086,217) and further in view of Yamamoto et al (US Patent #4,515,162) or Hostettler et al (US Patent # 5,576,072).

The disclosure by Dolzhikov et al on the polymer/electrolyte is set forth as described above.

Dolzhikov et al do not disclose the use of pharmaceuticals, plasticizer, silica and other solvents such as alcohol.

Yamomoto et al disclose a coating for bio-electrode pad comprising of polyacrylic acid in water, cross-linking component, tackiness being controlled by cross-linking, additives such as PEG, NaCl, a flexibility imparting agent (plasticizer), and an antifungal agent or the like (Col-2, Lines: 1-54).

Hostettler et al disclose a process for making medical devices with a coating of commingled hydrogel based on polyurethane-polyurea (PU/PUR) hydrogel (Abstract). Hostettler further discloses the use of PEO in water with a molecular wt of 100,000 to 5,000,000 for the preparation of hydrogels commingled with PU/PUR, use of isopropanol to purify polyethers, and the incorporation of thixotropic agents such as amorphous silica which influence the quality and application of coatings to various substrates (Col-25, Lines: 40-68; Col-30, Lines: 30, Lines: 50-60; Col-35, Lines: 45-51).

It would be in the purview of a skilled artisan to take the disclosure of Dolzhikov on the polymer/electrolyte composition and combine with the disclosure of Yamamoto on the tackifier/plasticizers/pharmaceuticals and Hostettler on the incorporation silica to improve the bonding of the film and make minor obvious modifications to the composition by the design choice to arrive at the instant claims of the applicants.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marks et al (US Patent # 3,357,930) disclose the making of electrically conductive transparent materials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kallambella Vijayakumar whose telephone number is 703-305-4931. The examiner can normally be reached on M-Th, 07:00 - 15.30 hrs, Fri: 05.30-14.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Yogendra Gupta can be reached on 703-308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

Art Unit: 1751

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

kmv

January 24, 2003.

Mark
Mark Kopec
Primary Examiner